

AMENDMENTS TO THE CLAIMS

Claims 1-21 (Canceled)

Claim 22 (Currently amended): A method for generating clinically relevant cell numbers of Th1 cells, comprising:

(a) collecting material containing mononuclear T lymphoid cells from a mammal;
(b) activating the T lymphoid cells to alter their cytokine production profile by causing differentiation of the cells into Th1 cell, wherein the cells are activated in the presence of either or both interferon- γ and IL-2 or anti-IL-4 antibody or α B7.2 mAb or TGF- β , whereby cells differentiate into Th1 cells; and

(c) in the absence of exogenous IL-2 H-2, inducing cell proliferation and expanding the cells under conditions that produce at least about 10^{10} cells/liter of a homogeneous population of Th1 cells, wherein:

a homogeneous population of Th1 cells comprises greater than about 50% Th1 cells; and

the resulting cells do not require co-infusion of IL-2 for activity.

Claim 23 (Previously presented): The method of claim 22, wherein the Th1 cells with altered cytokine profile are purified.

Claim 24 (Previously Presented): The method of claim 22, wherein the Th1 cells with altered cytokine profile are specific for a defined antigen.

Claim 25 (Previously Presented): The method of claim 23, wherein the Th1 cells with altered cytokine profile are specific for a defined antigen.

Claims 26-28 (Canceled)

Claim 29 (Currently amended): The method of claim [[28 22]], wherein anti-IL-4 monoclonal antibodies are also present during activation.

Claim 30 (Canceled)

Claim 31 (Previously Presented): The method of claim 22, wherein the cells are expanded in the presence of two or more monoclonal antibodies.

Claim 32 (Previously Presented): The method of claim 31, wherein the monoclonal antibodies are specific for CD3 or CD2, combined with any combination of monoclonal antibodies specific for one or more of the following: CD4, CD8, CD11a, CD27, CD28, CD44 and CD45RO.

Claim 33 (Original): The method of claim 22, wherein the cells are expanded in a hollow fiber bioreactor.

Claims 34-154 (Canceled)

Claim 155 (Currently amended): A method for generating clinically relevant numbers of Th1 cells for autologous cell therapy, comprising:

- (a) collecting material comprising body fluid or tissue containing mononuclear cells from a mammal;
- (b) treating the cells to induce differentiation of mononuclear cells into Th1 cells, wherein the cells are treated with either or both interferon- γ and IL-2, or anti-IL-4 antibody or α B7.2 mAb or TGF- β to induce differentiation of Th1 cells; and
- (c) contacting the resulting differentiated cells with two or more different activating proteins specific for cell surface proteins present on the cells in an amount sufficient to induce *ex vivo* cell expansion, whereby clinically relevant numbers of cells for autologous cell therapy are generated, wherein the contacting is effected in the absence of exogenous ~~cytokines~~ cytokines [[IL-2]].

Claim 156 (Previously Presented): The method of claim 155, wherein cells are purified from the material.

Claim 157 (Currently amended): The method of claim 155, wherein the treating ~~and contacting steps~~ step occurs in the absence of exogenous cytokines.

Claim 158 (Previously Presented): The method of claim 155, wherein the cells are specific for a selected antigen.

Claims 159-164 (Canceled)

Claim 165 (Previously Presented): The method of claim 155, wherein the proteins specific for cell surface proteins are one or more monoclonal antibodies specific for immune cell surface proteins.

Claim 166 (Previously Presented): The method of claim 165, wherein the monoclonal antibodies are specific for CD3 or CD2, combined with any combination of monoclonal antibodies specific for one or more antigens selected from the group consisting of CD4, CD8, CD11a, CD27, CD28, CD44 and CD45RO.

Claim 167 (Previously Presented): The method of claim 155, wherein cell expansion is effected in a hollow fiber bioreactor.

Claim 168 (Previously Presented): The method of claim 155, wherein the cells are expanded to about 10^9 cells or greater.

Claim 169 (Canceled)

Claim 170 (Currently amended): The method of claim 155, wherein the expanded cells are predominantly Th1, ~~Th2~~, ~~Th3~~ cells.

Claim 171 (Previously Presented): The method of claims 155, wherein the expanded cells are contained in a volume of one liter or less.

Claim 172 (Previously Presented): The method of claim 155, wherein the expanded cells are contained in a volume of about 500 mls or less.

Claims 173-210 (Canceled)

Claim 211 (Currently amended): A method for generating immune cells for autologous cellular immunotherapy, comprising:

collecting leukocyte containing material from a mammal;

differentiating the leukocytes into Th1 cells by contacting the cells with a composition comprising interferon- γ , or anti-IL-4 antibody or α B7.2 mAb or TGF- β ; and

exposing the leukocyte-containing material to two or more different mitogenic monoclonal antibodies to induce *in vitro* cell proliferation of Th1 cells sufficient for infusion into the mammal for use in an immunotherapy treatment, wherein the *in vitro* cell proliferation is produced without the use of exogenous interleukin-2.

Claim 212 (Previously Presented): The method of claim 211, wherein at least 10^{10} cells are produced.

Claim 213 (Previously Presented): The method of claim 211, wherein the cells are at a density of 1×10^8 cells/ml.

Claims 214-217 (Canceled)